

AMENDED VERSION

IN THE CLAIMS:

1. (Currently Amended) An isolated or recombinant immunogenic polypeptide comprising a *Lawsonia spp.* hemolysin polypeptide, ~~a variant, or a truncated variant thereof, wherein said variant or truncated variant mimics or cross-reacts with a B-cell or T-cell epitope of *Lawsonia spp.* hemolysin polypeptides~~as set forth in SEQ ID NO. 1.

2. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 1 wherein said polypeptide elicits the production of antibodies against *Lawsonia spp.* when administered to an avian or porcine animal.

3. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 1 which confers a protective immune response against *Lawsonia spp.* when administered to an avian or porcine animal.

4. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 1 wherein the *Lawsonia spp.* is *L. intracellularis*.

Claim 5 (canceled)

6. (Currently Amended) An isolated or recombinant immunogenic polypeptide comprising:

~~(i) a peptide, oligopeptide or polypeptide comprising an amino acid sequence which has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1; or~~

~~(ii) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence having at least about 50% sequence identity to amino acid residues 1 to 50 of SEQ ID NO: 1; or~~

~~(iii) a homologue or derivative of (i) or (ii) which mimics a B-cell or T-cell epitope of a *Lawsonia* spp. hemolysin polypeptide, wherein said polypeptide elicits the production of antibodies against *Lawsonia* spp. in a porcine or avian animal and said polypeptides confer a protective immune response against *Lawsonia* spp. in the porcine or avian animal.~~

Claims 7-9 (Cancelled)

10. (Currently Amended) The isolated or recombinant immunogenic

polypeptide of claim 86, wherein said protective immune response is induced in a porcine animal.

11. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 6 wherein the *Lawsonia spp.* is *L. intracellularis*.

Claim 12 (cancelled)

13. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 6 comprising the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the hemolysin-encoding nucleotide sequence of pALK12 (ATCC 207195).

14. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 13 consisting essentially of the amino acid sequence of SEQ ID NO: 1 or the amino acid sequence encoded by the hemolysin-encoding nucleotide sequence of pALK12 (ATCC 207195).

Claims 15 and 16 (cancelled)

17. (Previously Amended) The isolated or recombinant immunogenic

polypeptide of claim 6 comprising amino acid residues about 1 to about 50 of SEQ ID NO: 1 wherein said polypeptide elicits the production of antibodies against *Lawsonia intracellularis* when administered to an avian or porcine animal.

Claim 18 (cancelled)

19. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 17 which induces a protective immune response against *Lawsonia intracellularis* in a porcine or avian animal.

20. (Previously Amended) The isolated or recombinant immunogenic polypeptide of claim 19 which induces a protective immune response against *Lawsonia intracellularis* in a porcine animal.

21. (Currently Amended) A vaccine composition for the prophylaxis or treatment of infection of an animal by *Lawsonia* spp., said vaccine composition comprising an effective amount of an immunogenic component comprising an isolated or recombinant polypeptide having at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1 or at least about 50% sequence identity to amino acid residues 1 to 50 of SEQ ID NO: 1 or an

~~immunogenic homologue, or derivative thereof which is immunologically cross-reactive with *Lawsonia Intracellularis*~~; and one or more carriers, diluents or adjuvants suitable for veterinary or pharmaceutical use.

Claim 22 (cancelled)

23. (Previously Amended) The vaccine composition according to claim 21 wherein the isolated or recombinant polypeptide comprises the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the hemolysin-encoding nucleotide sequence of pALK12 (ATCC 207195).

Claims 24-26 (cancelled)

27. (Withdrawn) A combination vaccine composition for the prophylaxis or treatment of the infection of an animal by *Lawsonia* spp., said vaccine composition comprising:

(i) a first immunogenic component comprising an isolated or recombinant polypeptide having at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1 or at least about 50% sequence identity to amino acid residues 1 to 50 of SEQ ID NO: 1 or an immunogenic homologue or derivative thereof which is immunologically

cross-reactive with *Lawsonia intracellularis*;

(ii) a second immunogenic component comprising an antigenic *L. intracellularis* peptide, polypeptide or protein; and

(iii) one or more carriers, diluents or adjuvants suitable for veterinary or pharmaceutical use.

28. (Withdrawn) A vaccine vector comprising a polynucleotide that encodes the immunogenic polypeptide of SEQ ID NO: 1, a homologue or a variant thereof operably linked to a promoter.

29. (Withdrawn) The vaccine vector of claim 28 wherein the polynucleotide comprises SEQ ID NO: 2 a homologue, or derivative thereof which has at least about 70% sequence identity thereto.

30. (Withdrawn) The vaccine vector of claim 28 wherein the *Lawsonia* spp. is *L. intracellularis*.

31. (Withdrawn) A polyclonal or monoclonal antibody molecule that binds specifically to a hemolysin polypeptide or a derivative of an hemolysin

polypeptide from *Lawsonia* spp. wherein said derivative has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1.

32. (Withdrawn) The antibody molecule of claim 31 wherein the hemolysin polypeptide or derivative thereof comprises the amino acid sequence set forth in SEQ ID NO: 1.

33. (Withdrawn) The antibody molecule of claim 31 wherein the hemolysin polypeptide or derivative thereof comprises about amino acid 1 to amino acid 50 of SEQ ID NO: 1.

34. (Withdrawn) A method of diagnosing the infection of a porcine or avian animal by *Lawsonia intracellularis* or a microorganism that is immunologically cross-reactive thereto, said method comprising the steps of: contacting a biological sample derived from said animal with the antibody molecule of claim 31 for a time and under conditions sufficient for an antigen:antibody complex to form, and detecting said complex formation.

35. (Withdrawn) The method of claim 34 wherein the biological sample is selected from the group consisting of serum, lymph nodes, ileum, caecum, small intestine, large intestine, faeces or a rectal swab derived from a porcine

animal.

36. (Withdrawn) A method of identifying a previous or current infection with *Lawsonia intracellularis* or a microorganism that is immunologically cross-reactive thereto, said method comprising:

contacting blood or serum from said animal with the immunogenic polypeptide of claim 1 for a time and under conditions sufficient for an antigen: antibody complex to form; and detecting said complex formation.

37. (Withdrawn) An isolated polynucleotide encoding a peptide, oligopeptide or polypeptide selected from the group consisting of:

(i) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence which has at least about 70% sequence identity to the amino acid sequence set forth in SEQ ID NO: 1;

(ii) a peptide, oligopeptide or polypeptide which comprises an amino acid sequence which has at least about 50% sequence identity to amino acid residue 1 to about amino acid residue 50 of SEQ ID NO: 1; and

(iii) a homologue or derivative of (i) or (ii) which mimics a B-cell or T-cell epitope of or confers immunity against a *Lawsonia spp.* when injected into an animal.

38. (Withdrawn) The isolated polynucleotide of claim 37, wherein the peptide, oligopeptide or polypeptide comprises the amino acid sequence set forth in SEQ ID NO: 1 or the amino acid sequence encoded by the hemolysin-encoding nucleotide sequence of pALK12 (ATCC 207195), or about amino acid residue 1 to about amino acid residue 50 thereof, or a B-cell epitope or T-cell epitope thereof.

39. (Withdrawn) The isolated polynucleotide of claim 38 comprising SEQ ID NO: 2, a complement or variant thereof.

40. (Withdrawn) The isolated nucleic acid molecule of claim 39 consisting essentially of the nucleotide sequence of SEQ ID NO: 2 or a variant thereof

41. (Withdrawn) The isolated polynucleotide of claim 38 encoding from about amino acid residue 1 to about amino acid residue 50 of SEQ ID NO: 2 or a variant thereof.

42. (Withdrawn) The isolated polynucleotide of claim 41 consisting essentially of that portion which encodes about amino acid residue 1 to about amino acid residue 50 of SEQ ID NO: 2 or a variant thereof.

43. (Withdrawn) A method of detecting *Lawsonia intracellularis* or *Lawsonia spp.* in a biological sample from a porcine or avian animal subject, said method comprising:

hybridizing one or more probes or primers from SEQ ID NO: 2 or a complement thereto to said sample; and detecting said hybridization.

44. (Withdrawn) The method of claim 43 wherein the biological sample is selected from the group consisting of: serum, lymph nodes, ileum, caecum, small intestine, large intestine, faeces and a rectal swab from a porcine animal.

45. (Withdrawn) The method of claim 44 wherein the detection is by any nucleic acid based hybridization or amplification reaction.

46. (Withdrawn) A probe or primer comprising least about 15 contiguous nucleotides from SEQ ID NO: 2 or the complement thereof.

47. (Withdrawn) The plasmid pALK13 (ATCC Accession No. 207196).

48. (Withdrawn) The combination vaccine according to claim 27 wherein the second immunogenic component is selected from the group

USSN Number: 10/009,919
Attorney Docket No. 3153.00184/PC10563A

consisting of OmpH, FlgE, hemolysin and autolysin.